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EXAMINER
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MARTINEZ, BRITTANY M

ART UNIT	PAPER NUMBER
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1793

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/562,526	<b>Applicant(s)</b> CHANE-CHING ET AL.	
	<b>Examiner</b> BRITTANY M. MARTINEZ	<b>Art Unit</b> 1793	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 21 August 2009.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-15, 17 and 19-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15, 17 and 19-22 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                    | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)         | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                          |

**/Wayne Langel/**

**Primary Examiner, Art Unit 1793 DETAILED ACTION**

***Status of Application***

Applicants' arguments/remarks and amendments filed August 21, 2009, have been carefully considered. **Claims 1-15, 17 and 19-22** are pending in the instant application, with **Claims 1-13 and 17** amended. **Claims 1-15, 17 and 19-22** have been examined. **Claims 16 and 18** have been cancelled.

***Claim Rejections - 35 USC § 102/103***

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
1. **Claims 1-3, 5 and 7-9** are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Itoi et al. (US 6,159,437).
2. With regard to **Claims 1-3**, Itoi discloses a composition comprising separated calcium phosphate platelets which exhibit apatite structure and wherein the calcium phosphate platelets have a long-axis length of 30-300 nm and a 10-100 nm short-axis (Itoi, c. 2, l. 55-57; c. 3, l. 21-27). Itoi does not explicitly disclose deficient apatite structure. However, the instant Specification defines deficient apatite structure calcium phosphate as calcium phosphate with a Ca/P ratio of 1.25-1.67 (S. 0023), and Itoi discloses hydroxyapatite (Itoi, c. 2, l. 55-57),  $\text{Ca}_{10}(\text{PO}_4)_6(\text{OH})_2$ , which has a Ca/P molar

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ratio of 1.67. Thus, the calcium phosphate of Itoi would have deficient apatite structure to no less an extent than that of the instant application.

3. With regard to **Claim 5**, Itoi discloses a plurality of the platelets having an apatite structure (Itoi, c. 2, l. 55-57; c. 3, l. 21-27). Although Itoi does not explicitly disclose the platelets exhibiting a chemical shift of between 3 ppm and 3.4 ppm, measured by phosphorous-31 MAS NMR, the platelets of Itoi would be expected to exhibit a chemical shift of between 3 ppm and 3.4 ppm, measured by phosphorous-31 MAS NMR since the platelets of Itoi have an apatite structure.

4. With regard to **Claim 7**, Itoi discloses hydroxyapatite (Itoi, c. 2, l. 55-57),  $\text{Ca}_{10}(\text{PO}_4)_6(\text{OH})_2$ , which has a Ca/P molar ratio of 1.67.

5. With regard to **Claim 8**, Itoi discloses an aqueous dispersion comprising calcium phosphate platelets (Itoi, c. 2, l. 55-57; c. 3, l. 21-27 and 36-65).

6. With regard to **Claim 9**, Itoi discloses a colloidal dispersion comprising calcium phosphate platelets in an aqueous solution containing a dispersing agent (Itoi, c. 2, l. 55-57; c. 3, l. 21-27 and 36-65).

7. **Claims 1-3, 5 and 7-9** are also obvious over Lee because anticipation is the epitome of obviousness.

8. **Claims 1 and 2** are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Lee et al. (WO 00/15194).

9. With regard to **Claims 1 and 2**, Lee discloses a composition comprising separated calcium phosphate platelets which exhibit apatite structure and wherein the

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calcium phosphate platelets have a length of 300 nm (Lee, p. 10, l. 18-20; p. 15, l. 30-31; Claims 15-17). Lee does not explicitly disclose deficient apatite structure. However, the instant Specification defines deficient apatite structure calcium phosphate as calcium phosphate with a Ca/P ratio of 1.25-1.67 (S. 0023), and Lee discloses calcium phosphate with a Ca/P molar ratio of 1.3-1.75 (Lee, p.11, l. 19). Thus, the calcium phosphate of Lee would have deficient apatite structure to no less an extent than that of the instant application.

10. **Claims 1 and 2** are also obvious over Lee because anticipation is the epitome of obviousness.

11. **Claims 1 and 2** are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Roeder et al. (US 2003/0031698 A1).

12. With regard to **Claims 1 and 2**, Roeder discloses a composition comprising separated calcium phosphate platelets which exhibit monetite structure and wherein the calcium phosphate platelets have a length of between 1 nm and 500 nm (Roeder, "Abstract;" Fig. 2; Table 1; p. 2, 0014; p. 3, 0033 and 0035; p. 5, 0047).

13. **Claims 1 and 2** are also obvious over Roeder because anticipation is the epitome of obviousness.

***Claim Rejections - 35 USC § 103***

14. **Claims 3, 4, 6, 8 and 9** are rejected under 35 U.S.C. 103(a) as being unpatentable over Roeder et al. (US 2003/0031698 A1) as applied to **Claim 1** above, and further as discussed below, as applied in the prior Office action.

15. **Claims 10, 12-15, and 17** are rejected under 35 U.S.C. 103(a) as being unpatentable over Kumta et al. (US 7,247,288 B2) in view of Itoi et al. (US 6,159,437).

16. With regard to **Claim 10**, Kumta discloses a method for preparing separated nanocrystalline calcium phosphate platelets (Kumta, "Abstract") comprising the steps of: i) preparing a solution of calcium salt; ii) adding a phosphate solution to the solution obtained in step i) (Kumta, c. 14, l. 58-67; c. 15, l. 1-3; c. 18, l. 27-32 and 40-47), so as to obtain a calcium to phosphorus molar ratio of greater than 1.67 (Kumta, c. 4, l. 48-51), wherein the pH is maintained constant (Kumta, c. 6, l. 8-18); iii) heat treating the solution obtained in step ii) (Kumta, c. 15, l. 5-8; c. 18, l. 50-53); iv) separating the calcium phosphate platelets formed from the solution obtained in step iii) (Kumta, c. 15, l. 5-8); wherein in at least one of steps i) or ii), the solutions further comprise ammonium ions (Kumta, c. 1, l. 66; c. 8, l. 35-41). Kumta further discloses that the typical pH required for the production of nanocrystalline calcium phosphate platelets (a pH in excess of 11) "is not suitable for cell stability and growth. Therefore, there is a need for a much more effective and a biocompatible synthesis approach" (Kumta, c. 1, l. 64-67; c. 2, l. 11-20). The difference between the process of Kumta and that of **Claim 10** of the instant application is Kumta does not disclose the calcium phosphate platelets

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having a length of between 250 nm and 800 nm, adjusting the pH of the solution to a selected value of between 4 and 6, addition over a period of time of between 30 minutes and 4 hours, nor heat treating the solution obtained in step ii) at a temperature of between 50°C and 95°C. Kumta does not explicitly disclose deficient apatite structure. However, the instant Specification defines deficient apatite structure calcium phosphate as calcium phosphate with a Ca/P ratio of 1.25-1.67 (S. 0023), and Kumta discloses calcium phosphate with a Ca/P molar ratio of 1.67 (Kumta, c. 1, l. 64-67). Thus, the calcium phosphate of Kumta would have deficient apatite structure to no less an extent than that of the instant application.

17. With regard to **Claims 10 and 13**, Kumta further discloses that the reaction stoichiometry can be adjusted in such a way that the ratio of calcium ions to phosphate ions favors the formation of a particular size of calcium phosphate crystals (Kumta, c. 8, l. 6-9).

18. With regard to **Claim 12**, Kumta discloses  $\text{CaCl}_2$  and  $\text{Ca}(\text{NO}_3)_2$  as possible calcium salts (Kumta, c. 1, l. 66; c. 4, l. 53-57; c. 8, l. 27-35).

19. With regard to **Claim 13**, Kumta discloses the concentration of calcium salts in solution being 2 M (Kumta, c. 18, l. 28-30).

20. With regard to **Claim 14**, Kumta discloses  $(\text{NH}_4)_2(\text{HPO}_4)$  as a possible phosphate source for the phosphate solution (Kumta, c. 1, l. 66).

21. With regard to **Claim 15**, Kumta discloses the Ca/P molar ratio being greater than 1.67 (Kumta, c. 4, l. 48-51).

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22. Kumta does not disclose the temperature of the heat treatment in step iii) being between 60°C and 90°C (**Claim 17**).

23. With regard to **Claims 10 and 17**, expected pH, addition times, and heating temperatures are result effective variables since one of ordinary skill in the art would expect different properties in the process and resulting product as such parameters vary. Since pH, addition times, and heating temperatures are result effective variables, it is within the skill of one of ordinary skill in the art to develop a suitable solution pH range, addition time, and heat treating temperature range. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). It would have been obvious to one of ordinary skill in the art to modify the process of Kumta with the claimed pH in order to obtain “a much more effective and a biocompatible synthesis” process (Kumta, c. 1, l. 64-67; c. 2, l. 11-20).

24. Further, with regard to **Claims 10 and 17**, Itoi discloses a composition comprising separated calcium phosphate platelets which exhibit apatite structure and wherein the calcium phosphate platelets have a long-axis length of 30-300 nm and a 10-100 nm short-axis obtained by reaction at a temperature between room temperature and 100°C (Itoi, c. 2, l. 55-57; c. 3, l. 21-29). Itoi does not explicitly disclose deficient apatite structure. However, the instant Specification defines deficient apatite structure calcium phosphate as calcium phosphate with a Ca/P ratio of 1.25-1.67 (S. 0023), and Itoi discloses hydroxyapatite (Itoi, c. 2, l. 55-57),  $\text{Ca}_{10}(\text{PO}_4)_6(\text{OH})_2$ , which has a Ca/P molar ratio of 1.67. Thus, the calcium phosphate of Itoi would have deficient apatite structure to no less an extent than that of the instant application.

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25. Thus, it would have been obvious to one of ordinary skill in the art to modify the process of Kumta with the platelet size and heat treating temperature of Itoi in order to obtain a process capable of producing calcium phosphate platelets useful in an apatite slurry in which secondary apatite particles are substantially redispersed (Itoi, "Abstract").

26. **Claims 11 and 19-22** are rejected under 35 U.S.C. 103(a) as being unpatentable over Kumta et al. (US 7,247,288 B2) in view of Roeder et al. (US 2003/0031698 A1).

27. With regard to **Claim 11**, Kumta discloses a method for preparing separated nanocrystalline calcium phosphate platelets (Kumta, "Abstract") comprising the steps of: i) preparing a solution of calcium salt; ii) adding a phosphate solution to the solution obtained in step i) (Kumta, c. 14, l. 58-67; c. 15, l. 1-3; c. 18, l. 27-32 and 40-47), so as to obtain a calcium to phosphorus molar ratio of greater than 1.67 (Kumta, c. 4, l. 48-51), wherein the pH is maintained constant (Kumta, c. 6, l. 8-18); iii) heat treating the solution obtained in step ii) (Kumta, c. 15, l. 5-8; c. 18, l. 50-53); v) separating the calcium phosphate platelets formed from the solution obtained in step iii) (Kumta, c. 15, l. 5-8); wherein in at least one of steps i) or ii), the solutions further comprise ammonium ions (Kumta, c. 1, l. 66; c. 8, l. 35-41). Kumta further discloses that the typical pH required for the production of nanocrystalline calcium phosphate platelets (a pH in excess of 11) "is not suitable for cell stability and growth. Therefore, there is a need for a much more effective and a biocompatible synthesis approach" (Kumta, c. 1, l. 64-67; c. 2, l. 11-20). Kumta does not explicitly disclose deficient apatite structure. However, the instant Specification defines deficient apatite structure calcium phosphate as

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calcium phosphate with a Ca/P ratio of 1.25-1.67 (S. 0023), and Kumta discloses calcium phosphate with a Ca/P molar ratio of 1.67 (Kumta, c. 1, l. 64-67). Thus, the calcium phosphate of Kumta would have deficient apatite structure to no less an extent than that of the instant application. The difference between the process of Kumta and that of **Claim 11** of the instant application is Kumta does not disclose the calcium phosphate platelets having a length of between 250 nm and 800 nm, adjusting the pH of the solution to a selected value of between 4 and 6, addition over a period of time of between 30 minutes and 4 hours, Ca/P molar ratio of between 1 and 2.5, heat treating the solution obtained in step ii) at a temperature of between 50°C and 95°C, nor adjusting the pH of the solution obtained in step iii) to a value of between 8 and 9.5 (**Claim 11**).

28. With regard to **Claims 11 and 20**, Kumta further discloses that the reaction stoichiometry can be adjusted in such a way that the ratio of calcium ions to phosphate ions favors the formation of a particular size of calcium phosphate crystals (Kumta, c. 8, l. 6-9).

29. With regard to **Claim 19**, Kumta discloses  $\text{CaCl}_2$  and  $\text{Ca}(\text{NO}_3)_2$  as possible calcium salts (Kumta, c. 1, l. 66; c. 4, l. 53-57; c. 8, l. 27-35).

30. With regard to **Claim 20**, Kumta discloses the concentration of calcium salts in solution being 2 M (Kumta, c. 18, l. 28-30).

31. With regard to **Claim 21**, Kumta discloses  $(\text{NH}_4)_2(\text{HPO}_4)$  as a possible phosphate source for the phosphate solution (Kumta, c. 1, l. 66).

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32. With regard to **Claim 22**, Kumta discloses the Ca/P molar ratio being greater than 1.67 (Kumta, c. 4, l. 48-51).

33. With regard to **Claim 11**, expected pH, addition times, molar ratios, and heating temperatures are result effective variables since one of ordinary skill in the art would expect different properties in the process and resulting product as such parameters vary. Since pH, addition times, and heating temperatures are result effective variables, it is within the skill of one of ordinary skill in the art to develop a suitable solution pH range, addition time, molar ratio, and heat treating temperature range. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). It would have been obvious to one of ordinary skill in the art to modify the process of Kumta with the claimed pH in order to obtain "a much more effective and a biocompatible synthesis" process (Kumta, c. 1, l. 64-67; c. 2, l. 11-20).

34. Further, with regard to **Claim 11**, Roeder discloses a composition comprising calcium phosphate platelets which exhibit monetite structure and wherein the calcium phosphate platelets have a length of between 1 nm and 500 nm (Roeder, "Abstract;" Fig. 2; Table 1; p. 2, 0014; p. 3, 0033 and 0035; p. 5, 0047). Still further, Roeder discloses monetite (Roeder, Table 1),  $\text{CaHPO}_4$ , which has a Ca/P molar ratio of 1.

35. Thus, it would have been obvious to one of ordinary skill in the art to modify the process of Kumta with the platelets of Roeder in order to obtain a process capable of producing calcium phosphate platelets useful in composite biomaterials (Roeder, "Abstract").

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***Double Patenting***

36. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

37. **Claims 1-5, 8-15, 17 and 19-22** are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over Claims 1-4, 9, and 14-19 of copending Application No. 10/563167. Although the conflicting claims are not identical, they are not patentably distinct from each other because copending Application No. 10/563167 discloses a composition comprising separated calcium phosphate platelets, dispersions comprising separated calcium phosphate platelets, and a process for making such, substantially as in the instant claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

***Response to Amendment***

Applicants' amendments filed August 21, 2009, with respect to the Application Data Sheet, Abstract, Title, and Claims have been fully considered and are accepted. The objections to the Oath/Declaration, Specification, Abstract, and Claims and the 35 U.S.C. 112 rejections of the Claims in the previous Office action have been withdrawn.

***Response to Arguments***

2. Applicants' arguments filed August 21, 2009, have been fully considered but they are not persuasive.
3. Applicants' argument that Itoi does not describe monetite, predominant monetite or deficient apatite structure particles (Applicants' Response, 8/21/09, p. 10) is not convincing. The instant Specification defines deficient apatite structure calcium phosphate as calcium phosphate with a Ca/P ratio of 1.25-1.67 (S. 0023), and Itoi discloses hydroxyapatite (Itoi, c. 2, l. 55-57),  $\text{Ca}_{10}(\text{PO}_4)_6(\text{OH})_2$ , which has a Ca/P molar ratio of 1.67. Thus, the calcium phosphate of Itoi would have deficient apatite structure to no less an extent than that of the instant application.
4. Applicants' argument that Itoi does not describe separated calcium phosphate platelets (Applicants' Response, 8/21/09, p. 10-11) is not convincing. While the primary particles of Itoi eventually aggregate into particles having a size of 1 micrometer or more, the nanosize primary particles would initially be "separated" before said purposeful agglomeration. Thus, at some point, there would be a composition comprising separated calcium phosphate platelets which exhibit apatite structure and

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wherein the calcium phosphate platelets have a long-axis length of 30-300 nm and a 10-100 nm short-axis (Itoi, c. 2, l. 55-57; c. 3, l. 21-27).

5. Applicants' argument that Lee does not describe monetite, predominant monetite or deficient apatite structure particles (Applicants' Response, 8/21/09, p. 11-12) is not convincing. The instant Specification defines deficient apatite structure calcium phosphate as calcium phosphate with a Ca/P ratio of 1.25-1.67 (S. 0023), and Lee discloses calcium phosphate with a Ca/P molar ratio of 1.3-1.75 (Lee, p.11, l. 19). Thus, the calcium phosphate of Lee would have deficient apatite structure to no less an extent than that of the instant application.

6. Applicants' argument that Roeder does not describe separated calcium phosphate platelets (Applicants' Response, 8/21/09, p. 12) is not convincing. At some point, the composition of Roeder would be a composition comprising separated calcium phosphate platelets which exhibit monetite structure and wherein the calcium phosphate platelets have a length of between 1 nm and 500 nm (Roeder, "Abstract;" Fig. 2; Table 1; p. 2, 0014; p. 3, 0033 and 0035; p. 5, 0047). Even when the calcium phosphate particles are embedded in the thermoplastic material, they would be "separated" since, as Applicants' point out, they are not agglomerated.

7. Applicants' argument that Roeder does not describe calcium phosphate platelets having a length between 250 nm and 800 nm (Applicants' Response, 8/21/09, p. 12-13) is not convincing. Roeder discloses a composition comprising separated calcium phosphate platelets which exhibit monetite structure and wherein the calcium phosphate platelets have a length of between 1 nm and 500 nm (Roeder, "Abstract;" Fig. 2; Table

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1; p. 2, 0014; p. 3, 0033 and 0035; p. 5, 0047). **Claim 1** of the instant application does not require the majority of the particles to have the claimed length and does not preclude the inclusion of particles with a greater size.

8. Applicants' argument that "one skilled in the art would not have predicted the results achieved by the applicant based on the information available in the references cited by the Examiner" (Applicants' Response, 8/21/09, p. 13-14) is not convincing because it is not supported by any evidence of record. An expected platelet thickness is a result effective variable since one of ordinary skill in the art would expect different properties in the product as such thickness varies. Since the platelet thickness is a result effective variable, it is within the skill of one of ordinary skill in the art to develop a suitable calcium phosphate platelet thickness. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980). Applicants have not shown any evidence of unexpected results.

9. Applicants' argument that Kumta does not describe monetite, predominant monetite or deficient apatite structure particles (Applicants' Response, 8/21/09, p. 14-16) is not convincing. The instant Specification defines deficient apatite structure calcium phosphate as calcium phosphate with a Ca/P ratio of 1.25-1.67 (S. 0023), and Kumta discloses calcium phosphate with a Ca/P molar ratio of 1.67 (Kumta, c. 1, l. 64-67). Thus, the calcium phosphate of Kumta would have deficient apatite structure to no less an extent than that of the instant application. In any event, Kumta is modified with the calcium phosphate particle of Itoi. Itoi discloses a composition comprising separated calcium phosphate platelets which exhibit apatite structure and wherein the calcium phosphate platelets have a long-axis length of 30-300 nm and a 10-100 nm

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short-axis obtained by reaction at a temperature between room temperature and 100°C (Itoi, c. 2, l. 55-57; c. 3, l. 21-29). Itoi does not explicitly disclose deficient apatite structure. However, the instant Specification defines deficient apatite structure calcium phosphate as calcium phosphate with a Ca/P ratio of 1.25-1.67 (S. 0023), and Itoi discloses hydroxyapatite (Itoi, c. 2, l. 55-57),  $\text{Ca}_{10}(\text{PO}_4)_6(\text{OH})_2$ , which has a Ca/P molar ratio of 1.67. Thus, the calcium phosphate of Itoi would have deficient apatite structure to no less an extent than that of the instant application.

10. Acknowledgment is made of Applicants' argument that Kumta does not teach a process pH of between 4 and 6 (Applicants' Response, 8/21/09, p. 15-16); however, Kumta discloses that the typical pH required for the production of nanocrystalline calcium phosphate platelets (a pH in excess of 11) "is not suitable for cell stability and growth. Therefore, there is a need for a much more effective and a biocompatible synthesis approach" (Kumta, c. 1, l. 64-67; c. 2, l. 11-20). Thus, it would have been obvious to one of ordinary skill in the art to modify the process of Kumta with the claimed pH in order to obtain "a much more effective and a biocompatible synthesis" process (Kumta, c. 1, l. 64-67; c. 2, l. 11-20).

11. Applicants' argument that Itoi does not describe monetite, predominant monetite or deficient apatite structure particles (Applicants' Response, 8/21/09, p. 15) is not convincing. The instant Specification defines deficient apatite structure calcium phosphate as calcium phosphate with a Ca/P ratio of 1.25-1.67 (S. 0023), and Itoi discloses hydroxyapatite (Itoi, c. 2, l. 55-57),  $\text{Ca}_{10}(\text{PO}_4)_6(\text{OH})_2$ , which has a Ca/P molar

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ratio of 1.67. Thus, the calcium phosphate of Itoi would have deficient apatite structure to no less an extent than that of the instant application.

12. Applicants' argument that Itoi does not describe a process for producing calcium phosphate platelets (Applicants' Response, 8/21/09, p. 15) is not convincing. Itoi discloses a composition comprising separated calcium phosphate platelets which exhibit apatite structure and wherein the calcium phosphate platelets have a long-axis length of 30-300 nm and a 10-100 nm short-axis obtained by reaction at a temperature between room temperature and 100°C (Itoi, c. 2, l. 55-57; c. 3, l. 21-29).

13. Applicants' argument that Roeder does not describe a specific process for producing calcium phosphate platelets (Applicants' Response, 8/21/09, p. 16) is not convincing. Roeder was used merely to disclose desirable platelets. Roeder was not used to disclose a specific process or a process pH. It would have been obvious to one of ordinary skill in the art to modify the process of Kumta with the platelets of Roeder in order to obtain a process capable of producing calcium phosphate platelets useful in composite biomaterials (Roeder, "Abstract").

14. Applicants' argument that copending Application No. 10/563167 requires the presence of a polymer which complexes calcium in the composition or the reaction solution used to produce the composition (Applicants' Response, 8/21/09, p. 16-17) is not convincing. The nonstatutory obviousness-type double patenting rejection was used to show that the instant Claims are obvious over that of copending Application No. 10/563167, not the other way around. Thus, it is not necessary for the examiner to

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show that it would be obvious to add a polymer which complexes calcium in the composition or the reaction solution used to produce the composition.

### ***Conclusion***

15. Applicants' amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicants are reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRITTANY M. MARTINEZ whose telephone number is (571) 270-3586. The examiner can normally be reached on Monday-Friday 8:30AM-5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Stanley Silverman can be reached on (571) 272-1358. The fax phone

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number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Wayne Langel/  
Primary Examiner, Art Unit 1793

BMM  
/Brittany M Martinez/  
Examiner, Art Unit 1793